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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,502	07/23/2003	Kyoichi Sumida	14633.1US01	1967

7590	05/07/2007
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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/626,502

Applicant(s)

SUMIDA ET AL.

Examiner

Brandon J. Fetterolf, PhD

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8-12,14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11,12,14 and 16 is/are allowed.
- 6) ☒ Claim(s) 1 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/2007 has been entered.

Claims 1, 8-12, 14 and 16 are currently pending and under consideration.

The Declaration under 37 CFR 1.132 filed by the inventor, Kyoichi Sumida, on 12/27/2006 is sufficient to overcome the rejection of claims 1, 8-12, 14 and 16 under 35 U.S.C. 103(a) as being unpatentable over Eda et al. (U.S. 6248,597, 2001) in view of Shigenobu et al. (WO 02/018953, 2002) and in further view of Craig et al. (US 4,401,765, 1983) because the Declaration, as well as Applicants arguments set forth that there is no reasonable suggestion or motivation for combining the above references to form the claimed invention. In particular, while Shigenobu et al. teach a method of improving the reproducibility of an agglutination immunoassay comprising allowing an antigenic substance in a sample to bind to insoluble carrier particles and allowing an antibody or an antibody complex which reacts specifically to the antigenic substance to bind to the antigenic substance in the presence of a polymer, wherein the polymer includes either a polymer having a monomer unit derived from the patently disclosed monomer represented by the general formula [2], wherein the monomer represented by formula [2] is that of 2-methacryloyloxethyl phosphorylcholine (see Sakaki et al. J. Biomedical Materials Research 1999; 47: 523-528 for structure) or a copolymer obtained by polymerizing the monomer represented by 2-methacryloyloxethyl phosphorylcholine with a "second" monomer selected from the group consisting of (meth)acrylates such as acrylate ester, a methacrylate ester, butyl methacrylate or styrene derivatives (page 2, line 25 and lines 43+), the prior art does not appear to provide any motivation to modifying the polymer taught by Shigenobu et al. with an aralkyl methacrylate such as benzyl methacrylate in the context of the claimed invention. As such, the rejection of claims 1, 8-12, 14 and 16 under 35 U.S.C. 103(a) as being unpatentable over Eda et al. (U.S. 6248,597, 2001) in

Art Unit: 1642

view of Shigenobu et al. (WO 02/018953, 2002) and in further view of Craig et al. (US 4,401,765, 1983) is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a contacting step, wherein a sample is contacted with an antibody specific for prostate specific antigen in the presence of a copolymer, and a determining step, wherein the presence of prostate-specific antigen is based on the binding of an antibody specific for prostate specific antigen to prostate specific antigen. In the instant case, the claims encompass the active steps of "performing an antigen-antibody reaction" in the presence of a copolymer and determining the presence of prostate-specific antigen based on the antigen-antibody reaction. However, the recitation of "performing an antigen-antibody reaction" is unclear because it cannot be ascertained as to what this entails. Similarly, the recitation of "determining the presence of prostate-specific antigen based on the antigen-antibody reaction" is unclear because it cannot be ascertained what the antigen-antibody reaction entails.

Conclusion

Claims 11-12, 14 and 16 which are drawn to a kit of reagent for immunoassay of a prostate-specific antigen comprising a reagent containing a copolymer obtained by polymerizing a monomer represented by the general formula 2 with an alkyl methacrylate; and a reagent containing an antibody to a prostate specific antigen or a prostate specific antigen appears to be free of the prior art. In the instant case, Shigenobu et al. (WO 02/018953, 2002), as taught in the previous office action, is considered to be the closest prior art, but does not teach or suggest a copolymer obtained

Art Unit: 1642

by polymerizing a monomer represented by formula 2 with a aralkyl methacrylate. As such, claims 11-12, 14 and 16 appear to be in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

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